In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1670V
Filed: February 2, 2018

JENNIFER REED, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Entitlement; Ruling on the Record; Decision Without a Hearing; Causation-In-Fact**;** Tetanus-diphtheria-acellular pertussis ("Tdap") Vaccine**;** Shoulder Injury Related to Vaccine Administration (SIRVA)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Darryl R. Wishard, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT [1]

Dorsey, Chief Special Master:

On December 20, 2016, Jennifer Reed ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, *et seq*.[2] (the "Vaccine Act" or "Program"), alleging that as a result of receiving a tetanus-diphtheria-acellular pertussis ("Tdap")vaccination on March 28, 2016, she suffered from a shoulder injury related to vaccine administration ("SIRVA"). Petition at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters. For the reasons discussed herein, the undersigned finds that petitioner is entitled to compensation.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Petitioner filed medical records in support of her December 20, 2016 petition. Pet's Exs. 1-5, ECF No. 6; Pet's EXs. 6 & 7, ECF No. 9. An initial status conference was held on February 17, 2017. Order, ECF No. 10. During that conference, a schedule was set for respondent to file initial feedback in the case and petitioner was directed to provide respondent with a settlement demand. *Id.*

Petitioner forwarded a settlement demand for respondent's review on March 31, 2017. *See* Pet's Status Report, ECF No. 14. On May 12, 2017, respondent filed a status report stating that his review of the case was complete and an indicating an interest in pursuing litigative risk settlement. Resp.'s Status Report, ECF No. 17. A schedule was set for the parties to report on the progress of settlement discussions. Order, ECF No. 18.

On May 16, 2017, respondent informed the court via email that the parties had reached a tentative settlement agreement and requested that the undersigned issue a 15-week stipulation order. Order, ECF No. 19 (withdrawn). An October 13, 2017 deadline was set for the filing of the parties' stipulation of settlement. *Id.*

Less than one month later, respondent reported that the authorized representative of the Attorney General had declined to grant settlement approval for the parties' proposed tentative settlement. Resp.'s Status Report, ECF No. 20. The undersigned ordered respondent to file a Rule 4(c) report, ECF No. 21, and withdrew the May 17, 2017 15-week stipulation order, ECF No. 23.

Respondent filed his Rule 4(c) report on June 28, 2017, ECF No. 22. In this report, respondent argued that petitioner failed to meet her burden of proof and was not entitled to compensation for her alleged vaccine injury. Resp.'s Rule 4(c) Report at 1 & 7.

Petitioner was afforded time to file additional evidence. Order, ECF No. 24. In August 2017, petitioner filed affidavits from herself (Ex. 8), her coworker, Jolynn LaChance (Ex. 9), and her daughter, Kiara Reed (Ex. 11). ECF Nos. 27 & 28. Petitioner also filed her payroll records. ECF No. 27 (Ex. 10).

A status conference was held on September 5, 2017. Order, ECF No. 30. Following that conference, respondent was directed to file a status report setting forth his position in the case in light of petitioner's newly filed evidence. *Id.*

Two days later, respondent filed a status report stating a position that the case could not be settled and requesting a ruling on the record regarding entitlement. ECF No. 31. The undersigned ordered the parties to file concurrent motions for ruling by October 10, 2017.

On September 14, 2017, petitioner filed updated medical records (Exs. 12 & 13). ECF No. 33. On October 6, 2017, Respondent filed a status report indicating that he

would rely upon his June 28, 2017 Rule 4(c) report in lieu providing a motion for ruling. ECF No. 34.

Petitioner filed her motion for ruling on the record on October 10, 2017, ECF No. 35. No responses were ordered and the matter is now ripe for ruling. *See* Order, ECF No. 32.[3]

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory

[3] Petitioner filed additional updated medical records (Pet.'s Ex. 14) on January 29, 2018, ECF No. 36.

> causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. *Id.*

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. *See* § 11(c)(1)(A),(B),(D) and (E). With regard to duration, a petitioner must establish she

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization **and** surgical intervention.

§ 11(c)(1)(D) (emphasis added).

III. Analysis - Althen Prongs

a. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. *See Pafford v. Sec'y of Health & Human Servs.*, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. *See, e.g.*, *Pafford*, 451 F.3d at 1355 (reputable); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

i. SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the

alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy). *Id.; see also* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

1. The elements of petitioner's SIRVA claim

The undersigned's findings and conclusions are as follows:

a. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed Ms. Reed's medical history prior to her Tdap vaccination. Petitioner did not have a history of pain, inflammation or dysfunction of her right shoulder prior to vaccination.[4] Thus, petitioner satisfies this criterion.

b. Onset occurred within the specified time frame.

Respondent argues that petitioner has not established that her right shoulder pain began within 48 hours from her March 28, 2016 Tdap vaccination. Resp.'s Rule 4(c) Report at 6. In support of this assertion respondent refers to the call placed by petitioner to her gynecologist's office on April 8, 2016. [5] *Id.* at 6. Respondent infers that petitioner's report of difficulty raising her arm for three days prior to the call equates to her pain starting at that point three days earlier, or, eight days after vaccination. On the contrary, petitioner's call to her gynecologist does not appear to state when her pain started. Instead, petitioner related that she was experiencing pain at the Tdap injection site and difficulty raising her arms for three days. The undersigned does not agree that this report specifies the onset of petitioner's pain.

Likewise, respondent refers to a report provided by petitioner to her primary care physician on April 13, 2016 as a basis for finding that petitioner's pain began more than 48 hours after her March 28, 2016 Tdap vaccination. Resp.'s Rule 4(c) Report at 6. The records from that appointment include the following history: "right arm pain which started after a tetanus injection . . . patient received a tetanus vaccination at her GYNs office approximately 2-1/2 weeks ago on March 28 and one week after the injection she started

[4] Petitioner was previously treated for thoracic syrinx during which she reported pain numbness down her arms and pain in her back and left shoulder. Pet.'s Ex. 2 at 11-12.

[5] Respondent incorrectly states that petitioner placed the call to her primary care physician rather than her gynecologist's office were the shot was administered. *Compare* Resp.'s Rule 4(c) Report at 6, *with* Resp.'s Rule 4(c) Report at 2 & Pet.'s Ex. 2 a 7 (gynecologist's records).

to notice intense pain involving her right upper arm." Pet.'s Ex. 3 at 42. As this record is somewhat ambiguous as to whether petitioner intended to report the intensity of her pain increasing after one week, or starting after one week, the undersigned will instead consider the evidence of onset as a whole taking into account petitioner's proffered affidavits and payroll records.

Relying on his Rule 4(c) report which was filed prior to petitioner's affidavits and payroll records (Pet.'s Exs. 8-11), respondent has not provided a brief on the issue of onset that evaluates all of petitioner's evidence.

Petitioner claims that she immediately began to have pain in her right shoulder following the vaccination at issue. Pet.'s Ex. 8 ¶ 3. Petitioner states that her pain was so severe she was unable to immediately return to work. *Id.* at ¶4. Petitioner's payroll records confirm that she did not clock-in for two days following her Tdap vaccination and was afforded two hours of sick leave on March 31, 2016. Pet.'s Ex. 10. Ms. Jolynn LaChance, petitioner's coworker, also recalls petitioner being unable to work on March 29, 2016 due to severe shoulder pain. Pet.'s Ex. 9. Petitioner's daughter, Kiara Reed, also averred that during a visit with her mother on March 28, 2016 after the vaccination petitioner reported being in extreme pain. Pet.'s Ex. 11.

Based upon the evidence set forth in the medical records, affidavits, and payroll records the undersigned finds that the onset of petitioner's shoulder pain was within 24 hours of the March 28, 2016 Tdap vaccination, and therefore, is within the specified time frame of $\leq$48 hours.

c. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

The evidence submitted by petitioner includes medical records detailing the treatment which she sought for pain in her right shoulder over nearly two years since her March 2016 Tdap vaccination. A summary of these records follows below.

Petitioner reported pain in her right arm to her gynecologist on April 8, 2018, and was prescribed a Lidoderm patch for the pain. Pet.'s Ex. 2 at 7. On April 13, 2016, petitioner was seen by Angela Karavasilis, D.O. for continued right arm pain. Pet.'s Ex. 3 at 42. Dr. Karavasilis noted that petitioner had "tenderness to palpation over the right bicep tendon and in the general area of her R humerus. She has significant weakness to isometric resistance on the right compared to the left upper extremity." Id. at 44. Petitioner was referred for an x-ray and evaluation by an orthopedist. *Id.* at 45. Petitioner's April 13, 2016 right shoulder x-ray revealed "no evidence for fracture, dislocation or arthritic joint disease." Pet.'s Ex. 3 at 135.

On April 15, 2016, petitioner was seen by an orthopedic surgeon[6] for continued "right arm pain after tetanus shot." Pet.'s Ex. 3 at 142. The records from this encounter

[6] The records generated by petitioner's orthopedist, Dr. Albert Tom, incorrectly state the date of petitioner's Tdap vaccination as April 1, 2016.

include the following history: "developed soreness at the injection site and [is unable] (sic) to move her arm complaining of intense pain . . . pain is primarily over the anterior arm and biceps region to the length of the bicep." *Id.* The orthopedist's impression was "right anterior arm pain along the biceps muscle and tendon, right shoulder pain, onset of symptoms after tetanus shot." *Id.* at 144. Petitioner was referred to physical therapy. *Id.*

Petitioner began physical therapy on May 11, 2016, and was scheduled for continued therapy sessions twice a week for six to eight weeks. Pet.'s Ex. 5 at 157. By August 24, 2016, petitioner had completed 14 physical therapy sessions. Pet.'s Ex. 5 at 69. During that time, petitioner remained under the care of her orthopedist and received a cortisone injection in her right shoulder on June 30, 2016. Pet.'s Ex. 3 at 148-49; Pet.'s Ex. 7 at 3. Petitioner saw a second orthopedist, Dr. Anthony R. Marino, on August 24, 2016. Pet.'s Ex. 4 at 25.

Having not seen significant improvement in her pain after physical therapy and cortisone treatment, petitioner underwent right shoulder arthroscopic debridement and right shoulder arthroscopic acromioplasty on September 27, 2016. Pet.'s Ex. 5 at 15. Petitioner returned to Dr. Marino for a post-operative follow-ups on October 5, 2016 and November 2, 2016 and reported soreness and pain in her right shoulder. Pet.'s Ex. 4 at 2, 27. Dr. Marino's post-operative assessment was "right shoulder tendonitis and subacromial irritation." *Id.* at 28.

Petitioner began a long-term pain management program for her right shoulder in May 2017. Pet.'s Exs. 12 & 14 *passim* (pain management records from May 2017 – January 2018).

Petitioner returned to orthopedist, Dr. Marino, on June 7, 2017, for a follow up of her right shoulder. Pet.'s Ex. 13 at 2. On examination, petitioner had "some pain with resistive function." *Id.* Dr. Marino offered petitioner another cortisone shot and recommended that she try relieving her pain with ice and anti-inflammatories with a hope for improvement over the long term. *Id.* No further intervention was recommended. *Id.*

Based on the records of petitioner's ongoing treatment summarized above, the undersigned finds that the pain and decreased range of motion petitioner experienced are limited to her right shoulder in which she received the Tdap vaccine. Thus, petitioner has satisfied this criteria.

d. No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

There is no evidence in the record that demonstrates any type of condition or abnormality that would explain petitioner's symptoms. *See* Pet.'s Ex. 3 at 135 (x-ray negative for fracture, dislocation, or arthritic disease).

ii. Logical sequence of cause and effect showing the vaccine was the reason for the injury

Guided by the criteria for evaluating a Table SIRVA injury, the undersigned finds that petitioner has shown, by a preponderance of the evidence, a logical sequence of cause and effect showing that her March 28, 2016 Tdap vaccine was the reason for her shoulder injury. The SIRVA criteria provides a perfectly logical sequence of cause and effect including (1) no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy). The undersigned has found, *infra*, that petitioner has satisfied all these requirements and thus has satisfied *Althen* prong two.

iii. Proximate temporal relationship between vaccination and injury

"The proximate temporal relationship prong [under *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. *See Langland v. Sec'y of Health & Human Servs.,* 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner's shoulder injury must begin within 48 hour or less of the vaccination. The undersigned has found that the onset of petitioner's shoulder injury began within 24 hours of the vaccination, and thus, petitioner has satisfied Althen prong two.

IV. Conclusion

A cause-in-fact injury is established when petitioner demonstrates by a preponderance of the evidence: (1) She received a vaccine set forth on the Vaccine Injury Table; (2) She received the vaccine in the United States; (3) She sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must establish each of three factors announced by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.* by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and

injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

In light of all of the above, and in view of the submitted evidence, including the medical records and the parties' respective motions, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master